

**mdi** AseptiSac™ A autoclavable single use bags with beta port are designed for transfer of sterile components into isolators or removal of aseptic waste out of isolators.

These fits onto alpha port on isolators, while maintaining the sterile contamination free environment.

### Sizes Available: Beta Port

- 190 mm



### Materials of Construction

<b>Flange and Cover</b>		High temperature polycarbonate
<b>Beta Seal</b>		Platinum cured silicone
<b>O-Ring</b>		Platinum cured silicone
<b>Weld Ring</b>		High density polyethylene (HDPE)
<b>Bag layers</b>	Top	High density polyethylene (HDPE)
	Bottom	Tyvek

### Applications

Aseptic manufacturing of drug products

### Unique Performance Advantages

- Removable/reusable handle system
- Fast and easy contamination free transfer
- Increased flexibility and reduced manufacturing time
- Minimize validation costs
- No decontamination
- No cleaning validation
- Minimized manual intervention

### Specifications

#### Sterilization by autoclaving

121°C for 30 minutes, 1 cycle

#### Bioburden Levels

Bioburden level is < 1000 cfu/bag as per ISO 11737-1

#### Bacterial Endotoxin Levels

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test as per USP <85>

#### Fiber Release

Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release

#### Particle Release

Complies with USP <788> test for particulate matter in injections